

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re Application of
Zucherman et al.

Serial No.: **10/694,103**

Filed: **October 27, 2003**

For: **Interspinous Process Implant with
Radiolucent Spacer and Lead-in Tissue
Expander**

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APPEAL BRIEF

(I.) REAL PARTY IN INTEREST

The real party in interest is Medtronic Spine L.L.C.

(II.) RELATED APPEALS AND INTERFERENCES

None.

(III.) STATUS OF CLAIMS

Claims 1-71 were originally pending in the case. Claims 68-71 have been canceled. Claims 1-67 remain in the case, stand finally rejected, and are being appealed herein.

(IV.) STATUS OF AMENDMENTS

All amendments have been entered in this case.

(V.) SUMMARY OF CLAIMED SUBJECT MATTER

There are five independent claims on appeal, claims 1, 19, 37, 47, and 62.

Claim 1 is directed to an implant adapted to be placed between spinous processes. The implant (element 100 in Fig. 1A) includes a radiopaque shaft (element 102 in Fig. 1A; Spec. ¶¶ [0015]-[16], [0021]), a spacer rotatably mounted on the shaft (element 350 in Figs. 3A-3C; Spec. ¶¶ [0033]-[35]), and a tissue expander that is at least in part radiolucent and extends from the shaft (element 110 in Fig. 1A; Spec. ¶¶

[0015], [0021]). The tissue expander distracts the soft tissue and the spinous processes while not impairing the ability to view the spinous processes in an x-ray (Spec. ¶¶ [0015], [0021]).

Claim 19 is directed to an implant adapted to be placed between spinous processes. The implant (element 100 in Fig. 1A) includes a body that includes a radiopaque shaft (element 102 in Fig. 1A; Spec. ¶¶ [0015]-[16], [0021]), a spacer rotatably mounted on the shaft (element 350 in Figs. 3A-3C; Spec. ¶¶ [0033]-[35]), and a tissue expander that extends from the shaft (element 110 in Fig. 1A; Spec. ¶¶ [0015], [0021]). The tissue expander is at least in part radiolucent and the spacer is at least in part radiolucent, with the partially radiolucent tissue expander distracting the soft tissue and the spinous processes while not impairing the ability to view the spinous processes in an x-ray (Spec. ¶¶ [0015], [0021]).

Claim 37 is directed to an implant adapted to be placed between spinous processes. The implant (element 100 in Fig. 1A) includes a body including a radiopaque shaft (element 102 in Fig. 1A; Spec. ¶¶ [0015]-[16], [0021]), a spacer rotatably mounted on the shaft (element 350 in Figs. 3A-3C; Spec. ¶¶ [0033]-[35]), and a tissue expander extending from the shaft wherein the tissue expander is at least in part radiolucent (element 110 in Fig. 1A; Spec. ¶¶ [0015], [0021]). The tissue expander is at least in part selected from the group consisting of polyetheretherketone, polyetherketoneketone, and polyaryletheretherketone, and the spacer is at least in part selected from the group consisting of polyetheretherketone, polyetherketoneketone, and polyaryletheretherketone (Spec. ¶¶ [0021]-[22], [0024]). The tissue expander distracts

the soft tissue and the spinous processes while not impairing the ability to view the spinous processes in an x-ray (Spec. ¶¶ [0015], [0021]).

Claim 47 is directed to an implant adapted to be placed between spinous processes. The implant (element 100 in Fig. 1A) includes a body with a radiopaque shaft (element 102 in Fig. 1A; Spec. ¶¶ [0015]-[16], [0021]), a spacer rotatably mounted on the shaft (element 350 in Figs. 3A-3C; Spec. ¶¶ [0033]-[35]), and a tissue expander extending from the shaft (element 110 in Fig. 1A; Spec. ¶¶ [0015]). The tissue expander is at least in part radiolucent (Spec. ¶¶ [0021]). The tissue expander is at least in part selected from the group consisting of polyetheretherketone, polyetherketoneketone, polyaryletheretherketone, polyetherketone, polyetherketoneetherketoneketone, and polyetheretherketoneketone (Spec. ¶¶ [0021]-[22], [0024]). The tissue expander distracts the soft tissue and the spinous processes while not impairing the ability to view the spinous processes in an x-ray (Spec. ¶¶ [0015], [0021]).

Claim 62 is directed to an implant adapted to be placed between spinous processes. The implant (element 100 in Fig. 1A) includes a body having a shaft extending therefrom (element 102 in Fig. 1A; Spec. ¶¶ [0015]-[16], [0021]), a spacer rotatably mounted on the shaft (element 350 in Figs. 3A-3C; Spec. ¶¶ [0033]-[35]), and a tissue expander extending from the shaft (element 110 in Fig. 1A; Spec. ¶¶ [0015]). The body and the shaft are radiopaque, and further wherein the spacer and the tissue expander are radiolucent, wherein the partially radiolucent tissue expander distracts the soft tissue and the spinous processes while not impairing the ability to view the spinous processes in an x-ray (Spec. ¶¶ [0021]).

(VI.) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 1, 3-4, 6-12, 14-20, 23-27, 29-31, and 33-36 are unpatentable under 35 U.S.C. 103(a) over U.S. Patent No. 6,048,342 (Zucherman '342) in view of U.S. Patent No. 4,834,757 (Brantigan '757) and in view of U.S. Patent Publication No. 2002/0016592 (Branch).

Whether claims 2, 13, 21-22, 63, and 66 are unpatentable under 35 U.S.C. 103(a) over U.S. Patent No. 6,048,342 (Zucherman '342) in view of U.S. Patent No. 4,834,757 (Brantigan '757), U.S. Patent Publication No. 2002/0016592 (Branch), and U.S. Patent No. 5,192,327 (Brantigan '327).

Whether claims 5 and 28 are unpatentable under 35 U.S.C. 103(a) over U.S. Patent No. 6,048,342 (Zucherman '342), U.S. Patent No. 4,834,757 (Brantigan '757), U.S. Patent Publication No. 2002/0016592 (Branch), and U.S. Patent Publication No. 2001/0012938.

Whether claims 37-41, 43-55, and 57-61 are unpatentable under 35 U.S.C. 103(a) over U.S. Patent No. 6,048,342 (Zucherman '342) in view of U.S. Patent No. 5,192,327 (Brantigan '327) and U.S. Patent Publication No. 2002/0016592 (Branch).

Whether claims 42 and 56 are unpatentable under 35 U.S.C. 103(a) over U.S. Patent No. 6,048,342 (Zucherman '342) and U.S. Patent No. 5,192,327 (Brantigan '327) and U.S. Patent Publication No. 2002/0016592 (Branch) in further view of U.S. Patent Publication No. 2001/0012938.

Whether claims 62, 64-65 and 67 are unpatentable under 35 U.S.C. 103(a) over U.S. Patent No. 6,048,342 (Zucherman '342) in view of the combination of U.S. Patent No. 4,834,757 (Brantigan '757) and U.S. Patent Publication No. 2002/0016592 (Branch).

Whether claims 63 and 66 are unpatentable under 35 U.S.C. 103(a) over U.S. Patent No. 6,048,342 (Zucherman '342) and U.S. Patent Publication No. 2002/0016592 (Branch) and U.S. Patent No. 4,834,757 (Brantigan '757) in view of U.S. Patent No. 5,192, 327 (Brantigan '327).

(VII.) ARGUMENT

A. Law of Obviousness

The PTO has the burden under 35 U.S.C. 103 to determine a prima facie case of obviousness. This determination is made by showing that a person of ordinary skill in the art would have been motivated to combine the prior art to achieve the claimed invention and whether there would have been a reasonable expectation of success in doing so. This determination is ultimately a legal question, but is based on a series of factual factors. These factors include (1) the scope and content of the prior art, (2) the differences between the prior art and the claimed invention, and (3) the level of ordinary skill in the pertinent art. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1731, 82 U.S.P.Q.2d 1385, 1391 (2007). An additional factor may include relevant secondary considerations, including commercial success, long felt but unsolved needs, and failure of others.

The determination of obviousness is not a rigid rule that applies to each case, but rather is flexible and expansive. *Id.* at 1739, 82 U.S.P.Q.2d at 1395. The determination should include an analysis of the pertinent facts for the case and an explanation as to why the invention is obvious. In view of this flexible and expansive approach, the PTO must articulate the facts for the specific case, and provide an explicit explanation of the reasoning to support a conclusion that the invention is obvious. The PTO cannot rely on conclusory statements. *In re Kahn*, 78 U.S.P.Q.2d 1329, 1335 (Fed. Cir. 2006). This detailed record then allows an Applicant to determine how to best proceed in the future. 35 U.S.C. § 132.

B. Independent claims 1 and 19 are not made obvious over Zucherman '342 in view of Brantigan '757 and Branch

Claims 1 and 19 are each directed to implants with certain elements that are radiopaque and certain elements that are at least in part radiolucent. Specifically, claim 1 includes, *inter alia*, an implant with a radiopaque shaft and a tissue expander that is at least in part radiolucent. Claim 19 includes, *inter alia*, an implant with a radiopaque shaft and a tissue expander and spacer that are both at least in part radiolucent. These elements of the implant are constructed of different materials to provide for different functions during insertion of the implant, in addition to after the implant has been inserted into the patient. One function of the radiolucent tissue expander and/or spacer is they do not block the view of the spine during x-ray imaging. Further, one function of the radiopaque shaft is it allows for determining the position of the implant during x-ray imaging. (Spec. ¶ 0021).

The Office Action admits that Zucherman '342 does not include an implant with a first portion that is radiolucent, or a second portion that is at least partially radiopaque (Office Action, page 3). The Office Action cites to Brantigan '757 for an implant that incorporates a radiolucent portion, and to Branch for an implant that is at least radiopaque. These references do not disclose these aspects.

Brantigan '757 discloses an implant that is entirely radiolucent (Col. 1, lines 32-35). It appears the reason for the entire implant to be radiolucent is to allow monitoring of bone growth with x-ray visualization (Col. 6, line 66 – Col. 7, line 5). There is no disclosure or suggestion within Brantigan '757 that only a discrete section of the implant be constructed of a radiolucent material and at least one second element be constructed at least in part of a radiopaque material. More particularly, there is no disclosure or suggestion that the tissue expander and spacer be constructed at least in part of a radiolucent material.

Branch discloses an interbody fusion graft and associated instrumentation, including an implant holder used for inserting the fusion graft into the patient. A gripping head of the implant holder may include a pin with a radiopaque portion to assist in viewing placement of the implant during surgery (§ 0009). **However, the radiopaque portion is on the tool and not on the implant itself.** Branch does not disclose itself that a discrete section of the implant can be constructed at least in part of a radiopaque material.

This combination does not disclose an implant with a shaft that is radiopaque, and a tissue expander and spacer that is at least in part radiolucent. Brantigan '757 discloses that the entire implant be constructed of a radiolucent material. Branch does

not disclose an implant that is radiopaque, but rather a radiopaque tool for inserting an implant. Therefore, this combination does not make either claim 1 or 19 obvious.

Further, the Office Action does not establish a prima facie case of obviousness. The Office Action includes a conclusory statement that Brantigan '757 makes obvious an implant that is partially constructed of a radiolucent material.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device the combination of Zucherman et al. '342 and Brantigan '757 having at least a partially radiolucent portion in view of Brantigan '757 to better allow the device to be seen during surgery in the presence of x-ray.
(Office Action, page 3)

However, there is no explanation how an implant that is completely constructed of a radiolucent material makes obvious an implant that is partially constructed of a radiolucent material. Further, the logic of the Office Action appears to be misguided because a radiolucent material cannot be seen during surgery in the presence of x-ray.

Likewise, the Office Action makes a conclusory statement that Branch makes obvious an implant partially constructed of a radiopaque material.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of the combination of Zucherman et al. '342 and Brantigan '757 having at least a portion radiopaque in view of Brantigan '342 [sic] to allow the device to be better viewed in surgery.
(Office Action, pages 3-4)

It is assumed that the Office Action meant to cite to Branch and not Brantigan '342 for the radiopaque portion. Regardless, the Office Action does not explain how the disclosure of Branch for a tool with a radiopaque portion makes obvious an implant with a radiopaque portion.

In rebutting these similar patentability arguments previously presented by the Applicant, the Office Action again provides conclusory statements as to how these references in combination make these claims obvious.

With regards to modification of the basic structure of the device, having either radiopaque or radiolucent materials present in the device would allow it to be used to better potential, and at least not impairing the ability to view the spinous processes in an x-ray at least to some degree, regardless of the level of material combination present in the device. It is further noted that it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate radiolucent or radiopaque materials in the device, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use (better viewing ability in a surgical application) as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.
(Office Action, page 7)

The explanation that these materials would allow the device to be used to better potential is a conclusory statement. Further, this explanation only addresses the aspect of radiolucent materials, and does not address the combination of radiopaque materials, and the placement of the radiolucent and radiopaque materials. Further, this explanation appears to address an implant that is constructed of one of a radiopaque or radiolucent material, and not an implant constructed of both. In sum, this explanation does not remedy the lack of establishing a prima facie case of obviousness in view of *Zucherman '342*, *Brantigan '757*, and *Branch*.

The Office Action cites to *In re Leshin* 125 USPQ 416 to support the conclusion that selection of a known material on the basis of its suitability for the intended use is an obvious design choice (Office Action, page 7). However, *Leshin* appears to apply to a much narrower fact pattern than the present application. *Leshin* included claims directed to a cosmetic container with specific claims directed to the container being

constructed of plastic. These claims were ultimately rejected over prior art that included a similar container made of molded plastic because substitution for one type of plastic for another was not a patentable aspect. In the present application, the inventive concept is at least an implant with sections constructed from materials with different properties (i.e., radiolucent and radiopaque). Further, the inventive concept is which elements of the implant are constructed from these materials. Zucherman '342, Brantigan '757, and Branch do not disclose these concepts and the narrow holding of *Leshin* is not applicable.

For at least these reasons, Zucherman '342, Brantigan '757, and Branch in combination or alone do not disclose an implant with a shaft that is radiopaque and a tissue expander that is at least in part radiolucent.

1. Dependent Claims 3-4, 6-12, 14-18, 20, 23-27, 29-31, and 33-36 depend from an allowable independent claim.

Claims 3-4, 6-12, and 14-18 all depend from claim 1. Claims 20, 23-27, 29-31, and 33-36 all depend from claim 19. Thus, the dependent claims are allowable for at least the same reasons given above.

2. Dependent claim 11 adds a patentably distinct limitation to claim 1.

Claim 11 depends from claim 1 and further adds that the body in the first wing is radiopaque such that under X-ray the implant resembles a T-shape. The Office Action makes a conclusory statement that Brantigan '757 discloses a spacer that would allow a T-shape combined with a radiopaque wing (Office Action, page 3). The reasoning that the combination of Zucherman '342 and Brantigan '757 makes obvious this claim is

incorrect because neither discloses separate sections of an implant being constructed from materials with different properties that cause for a T-shape during x-ray viewing. Further, the Office Action does not establish a prima facie case for obviousness in view of the terse explanation of how these references are combined together. As the Federal Circuit has explained, a prima facie case cannot be established with conclusory statements. *In re Kahn*, 78 U.S.P.Q.2d at 1335.

3. Dependent claim 12 adds a patentably distinct limitation to claim 1.

Claim 12 depends from claim 1 and further adds that the spacer is at least in part radiolucent. As explained above for claim 1, the cited combination does not make this aspect obvious.

4. Dependent claims 14 and 25 add patentably distinct limitations to their corresponding independent claim.

Claim 14 depends from claim 1 and claim 25 depends from claim 19. These claims further add, *inter alia*, that the body, shaft, and first and second wings are radiopaque and the tissue expander and spacer are radiolucent such that under imaging the implant resembles an H-shape. The combination of Zucherman '342, Brantigan '757, and Branch does not disclose these discrete sections include these properties. Further, the Office Action makes at best a conclusory statement that the subject matter of these claims is obvious, but does not appear to provide any explanation as to how this conclusion is reached. Conclusory statements are not

adequate for establishing a prima facie case for obviousness. *In re Kahn*, 78 U.S.P.Q.2d at 1335.

5. Dependent claim 24 adds a patentably distinct limitations to claim 19.

Claim 24 depends from claim 19 and includes, *inter alia*, the body and first wing are radiopaque and the tissue expander and spacer are radiolucent such that under imaging the implant resembles a T-shape. The combination of Zucherman '342, Brantigan '757, and Branch does not disclose these discrete sections include these properties. Further, the Office Action makes only a conclusory statement that the subject matter of these claims is obvious, but does not appear to provide any explanation as to how this conclusion is reached.

C. Dependent claims 2, 13, 21-22, 63, and 66 are not made obvious over Zucherman '342, Brantigan '757, Branch, and Brantigan '327

Claims 2 and 13 depend from claim 1. Brantigan '327 does not overcome the deficiencies in the rejection to claim 1 stated above in section (VII)B. For at least this reason, claims 2 and 13 are not made obvious over this combination.

Claims 21-22 depend from claim 19. Brantigan does not overcome the deficiencies in the rejection to claim 19 stated above in section (VII)B. For at least this reason, claims 21-22 are not made obvious over this combination.

Claims 63 and 66 depend from claim 62. The rejection of claims 63 and 66 is based on the rejection to independent claim 62 "as applied to claims 1, 19, and 62 above..." (Office Action, page 4). However, claim 62 was not rejected in any of the

previous sections of the Office Action (i.e., before page 4). Therefore, there is no reasoning as to why these claims were rejected and the rejection is conclusory. Claim 62 is rejected later under 35 U.S.C. 103(a) over the combination of Zucherman '342, Brantigan '757, and Branch (Office Action, page 6). Brantigan '327 does not overcome the deficiencies in the rejection to claim 62 stated below in section (VII)G. For at least these reasons, claims 63 and 66 are not made obvious over this combination.

D. Dependent claims 5 and 28 are not made obvious over Zucherman '342, (Brantigan '757), Branch, and U.S. Patent Publication No. 2001/0012938.

Claim 5 depends from claim 1. U.S. Patent Publication No. 2001/0012938 does not overcome the deficiencies in the rejection to claim 1 stated above in section (VII)B. For at least this reason, claim 5 is not made obvious over this combination.

Claim 28 depends from claim 19. U.S. Patent Publication No. 2001/0012938 does not overcome the deficiencies in the rejection to claim 19 stated above in section (VII)B. For at least this reason, claim 28 is not made obvious over this combination.

E. Independent claims 37 and 47 are not made obvious over Zucherman '342 in view of Brantigan '327 and Branch

Claims 37 and 47 require, *inter alia*, a radiopaque shaft and a tissue expander that is at least in part radiolucent. As stated above in Section (VII)B, these different properties provide for the shaft to be visible during x-ray imaging, while the expander is not visible. This allows a doctor to have a clearer view of the spine under x-ray imaging.

As stated above in Section (VII)B, Zucherman '342 and Branch do not disclose an implant with a shaft that is radiopaque. The Office Action includes Brantigan '327 to

teach the use of a polyether ketone in implants (Office Action, page 5). Brantigan '327 discloses an implant with a uniform construction of the same material. Materials may include a carbon fiber reinforced polymer such as polyetheretherketone, a radiolucent plastic, and an inert metal (Col. 3, lines 9-13, Col. 4, lines 1-4).

Brantigan '327 does not disclose that an implant may include separate sections that are constructed of materials with different properties. Specifically, there does not appear to be any disclosure that the implant may include a tissue expander that is constructed from the radiolucent material, and the shaft constructed of a radiopaque material.

Further, the Office Action includes conclusory statements that Brantigan '327 discloses an implant that includes separate sections constructed from different materials.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Zucherman et al. '342 having at least a tissue expander or spacer made at least partially of polyether ketone in view of Brantigan '327 to better view the device in use.

Office Action, page 5

The logic cited above that constructing the implant to provide a better view during use would seem to imply that the entire device be constructed from a material to improve the ability to be viewed.

The further explanation as to why these references disclose the claimed invention on page 7 of the Office Action do not remedy the conclusory nature of the rejection, or adequately address why these references make the present invention obvious for the same reasons stated above in Section (VII)B.

For at least these reasons, Zucherman '342, Brantigan '327, and Branch in combination or alone do not disclose an implant with a shaft that is radiopaque and a tissue expander that is at least in part radiolucent.

1. Dependent Claims 38-41, 43-46, 48-55, and 57-61 depend from an allowable independent claim.

Claims 38-41 and 43-46 depend from claim 37. Claims 48-55, and 57-61 depend from claim 47. Thus, these dependent claims are allowable for at least the same reasons given above.

2. Dependent claims 38 and 52 add patentably distinct limitations to their corresponding independent claims.

Dependent claim 38 depends from claim 37 and dependent claim 52 depends from claim 47. These claims include, *inter alia*, the body, shaft, and first and second wings being radiopaque such that the implant resembles an H-shape during imaging. None of the references either alone or in combination disclose an implant with these elements constructed from a radiopaque material to provide an H-shape to facilitate viewing of the implant under imaging. The Office Action provides at best conclusory statements as to how the cited references disclose these elements constructed of a radiopaque material.

3. Dependent claim 51 adds a patentably distinct limitation to independent claim 47.

Dependent claim 51 depends from claim 47 and includes the body and the first wing are radiopaque such that imaging the implant resembles a T-shape. The references do not disclose these elements being radiopaque for the implant to include a T-shape. Further, the Office Action does not establish a prima facie case for obviousness in view of the terse explanation of how these references are combined together. As the Federal Circuit has explained, a prima facie case can not be established with conclusory statements. *In re Kahn*, 78 U.S.P.Q.2d at 1335.

F. Dependent claims 42 and 56 are not obvious over Zucherman '342, Brantigan '327, Branch, and U.S. Patent Publication No. 2001/0012938.

Claim 42 depends from claim 37. U.S. Patent Publication No. 2001/0012938 does not overcome the deficiencies in the rejection to claim 42 stated above in section (VII)E. For at least this reason, claim 42 is not made obvious over this combination.

Claim 56 depends from claim 47. U.S. Patent Publication No. 2001/0012938 does not overcome the deficiencies in the rejection to claim 47 stated above in section (VII)E. For at least this reason, claim 56 is not made obvious over this combination.

G. Independent claim 62 is not made obvious over Zucherman '342 in view of Brantigan '757 and Branch

Claim 62 includes, *inter alia*, an implant with a body and shaft that are radiopaque, and the spacer and the tissue expander are radiolucent. For the reasons stated above in Section (VII)B, this combination of references does not make an implant with these elements obvious.

1. Dependent Claims 64-65 and 67 depend from an allowable independent claim.

Dependent claims 64-65 and 67 depend from claim 62. Thus, these dependent claims are allowable for at least the same reasons given above.

2. Dependent claim 67 adds a patentably distinct limitation to claim 62.

Claim 67 depends from claim 62 and includes, inter alia, the shaft and wings are a radiopaque "H" on imaging film. For the reasons stated above in sections (VII)B and (VII)B2, this claim is not made obvious. Further, the Office Action provides only conclusory statements as to why the references make the claim obvious.

H. Dependent claims 63 and 66 are not obvious over Zucherman '342, Branch, Brantigan '757, and Brantigan '327.

Claims 63 and 66 depend from claim 62. Brantigan '327 does not overcome the deficiencies in the rejection to claim 62 stated above in section (VII)G. For at least this reason, claims 63 and 66 are not made obvious over this combination.

(VIII). CLAIMS APPENDIX

1. An implant adapted to be placed between spinous processes comprising:
a body that includes a shaft; wherein the shaft is radiopaque;
a spacer rotatably mounted on the shaft; and

a tissue expander extending from the shaft;

wherein the tissue expander is at least in part radiolucent, wherein the partially radiolucent tissue expander distracts the soft tissue and the spinous processes while not impairing the ability to view the spinous processes in an x-ray.

2. The implant of claim 1 wherein the tissue expander is selected from the group consisting of polyetheretherketone, polyetherketoneketone, polyaryletheretherketone, polyetherketone, polyetherketoneetherketoneketone, and polyetheretherketoneketone.

3. The implant of claim 1 wherein the spacer has a cross-sectional shape selected from the group consisting of elliptical-shaped, cylindrical-shaped, ovoid-shaped, oval-shaped, track-shaped, and rectangular-shaped with curved ends.

4. The implant of claim 1 wherein the spacer has a dimension selected from the group consisting of 6 mm, 8 mm, 10 m, 12 mm, and 14 mm.

5. The implant of claim 1 wherein the spacer has an off-center bore that receives the shaft so that the spacer can rotate about the shaft.

6. The implant of claim 1 wherein the tissue expander has a generally increasing cross-section from an end location to a location adjacent to the spacer.

7. The implant of claim 1 wherein the body includes a first wing extending from a location on the shaft on an opposite side of the spacer from which the tissue expander extends.
8. The implant of claim 1 wherein the shaft includes an attachment to which the tissue expander is affixed.
9. The implant of claim 8 wherein the attachment includes a device for receiving a wing.
10. The implant of claim 1 wherein the body includes a first wing extending from a location on the shaft on an opposite side of the spacer from which the tissue expander extends.
11. The implant of claim 10 wherein the body and the first wing are radiopaque such that under x-ray the implant resembles a T-shape.
12. The implant of claim 1 wherein the spacer is at least in part radiolucent.
13. The implant of claim 12 wherein at least one of the spacer and the tissues expander are selected from the group consisting of polyetheretherketone, polyetherketoneketone, polyaryletheretherketone, polyetherketone, polyetherketoneetherketoneketone, and polyetheretherketoneketone.

14. The implant of claim 1 further including:

a first wing located at one end of the shaft and a second wing located adjacent to the tissue expander such that the spacer is located between the first and the second wings, wherein the body, the shaft, and the first and second wings are radiopaque and the tissue expander and spacer are radiolucent such that under imaging the implant resembles an H-shape.

15. The implant of claim 1 wherein the shaft includes an attachment to which the tissue expander is molded.

16. The implant of claim 15 wherein the attachment includes a device for receiving a wing.

17. The implant of claim 1 wherein the spacer includes:

an inner spacer that is rotatably mounted about the shaft; and
an outer spacer that is movably mounted on the inner spacer.

18. The implant of claim 17 wherein:

the inner spacer has one of flattened or slightly radiused upper and lower surfaces and rounded ends; and

the outer spacer has one of flattened or slightly radiused upper and lower surfaces and rounded ends.

19. An implant adapted to be placed between spinous processes comprising:
a body that includes a shaft; wherein the shaft is radiopaque; and
a spacer rotatably mounted on the shaft;
a tissue expander extending from the shaft;
wherein the tissue expander is at least in part radiolucent, and
wherein the spacer is at least in part radiolucent, wherein the partially radiolucent tissue expander distracts the soft tissue and the spinous processes while not impairing the ability to view the spinous processes in an x-ray.

20. The implant of claim 19 including a wing located adjacent to the spacer.

21. The implant of claim 19 wherein at least one of the spacer and the tissues expander are selected from the group consisting of polyetheretherketone, polyetherketoneketone, polyaryletheretherketone, polyetherketone, polyetherketoneetherketoneketone, and polyetheretherketoneketone.

22. The implant of claim 19 wherein the tissue expander is selected from the group consisting of polyetheretherketone, polyetherketoneketone, polyaryletheretherketone, polyetherketone, polyetherketoneetherketoneketone, and polyetheretherketoneketone.

23. The implant of claim 19 wherein the tissue expander has a generally increasing cross-section from a distal end to a location adjacent to the spacer.

24. The implant of claim 19 wherein the implant has a first wing wherein the body and the first wing are radiopaque and the tissue expander and the spacer are radiolucent such that under imaging the implant resembles a T-shape.

25. The implant of claim 19 further including:

a first wing located at one end of the shaft and a second wing located adjacent to the tissue expander such that the spacer is located between the first and the second wings, wherein the body, the shaft, and the first and second wings are radiopaque and the tissue expander and spacer are radiolucent such that under imaging the implant resembles an H-shape.

26. The implant of claim 19 wherein the spacer has a cross-sectional shape selected from the group consisting of elliptical-shaped, cylindrical-shaped, ovoid-shaped, oval-shaped, track-shaped, and rectangular-shaped with curved ends.

27. The implant of claim 19 wherein the spacer has a dimension selected from the group consisting of 6 mm, 8 mm, 10 m, 12 mm, and 14 mm.

28. The implant of claim 19 wherein the spacer has an off-center bore that receives the shaft so that the spacer can rotate about the shaft.

29. The implant of claim 19 wherein the spacer includes:

an inner spacer that is rotatably mounted about the shaft; and

an outer spacer that is movably mounted on the inner spacer.

30. The implant of claim 27 wherein:

the inner spacer has one of flattened or slightly radiused upper and lower surfaces and rounded ends; and

the outer spacer has one of flattened or slightly radiused upper and lower surfaces and rounded ends.

31. The implant of claim 19 wherein the body includes a first wing extending from a location on the shaft on an opposite side of the spacer from which the tissue expander extends.

32. The implant of claim 31 wherein the body and the first wing are radiopaque and the tissue expander and spacer are radiolucent such that under imaging the implant resembles a T-shape.

33. The implant of claim 19 wherein the shaft includes an attachment to which the tissue expander is affixed.

34. The implant of claim 33 wherein the attachment includes a device that can receive a wing.

35. The implant of claim 19 wherein the shaft includes an attachment to which the tissue expander is molded.

36. The implant or claim 35 wherein the attachment includes a device that can receive a wing.

37. An implant adapted to be placed between spinous processes comprising:
a body including a shaft; wherein the shaft is radiopaque;
a spacer rotatably mounted on the shaft;
a tissue expander extending from the shaft wherein the tissue expander is at least in part radiolucent; and
wherein the tissue expander is at least in part selected from the group consisting of polyetheretherketone, polyetherketoneketone, and polyaryletheretherketone ; and
wherein the spacer is at least in part selected from the group consisting of polyetheretherketone, polyetherketoneketone, and polyaryletheretherketone, wherein the tissue expander distracts the soft tissue and the spinous processes while not impairing the ability to view the spinous processes in an x-ray.

38. The implant of claim 37 further including:
a first wing located at one end of the shaft and a second wing located adjacent to the tissue expander such that the spacer is located between the first and the second wings, wherein the body, the shaft, and the first and second wings are radiopaque such that under imaging the implant resembles an H-shape.

39. The implant of claim 37 wherein the shaft includes an attachment to which the tissue expander is molded.

40. The implant of claim 37 wherein the spacer has a cross-sectional shape selected from the group consisting of elliptical-shaped, cylindrical-shaped, ovoid-shaped, oval-shaped, track-shaped, and rectangular-shaped with curved ends.

41. The implant of claim 37 wherein the spacer has a dimension selected from the group consisting of 6 mm, 8 mm, 10 m, 12 mm, and 14 mm.

42. The implant of claim 37 wherein the spacer has an off-center bore that receives the shaft so that the spacer can rotate about the shaft.

43. The implant of claim 37 wherein the shaft includes an attachment to which the tissue expander is affixed.

44. The implant of claim 43 wherein the attachment includes a device for receiving a wing.

45. The implant of claim 37 wherein the spacer includes:
an inner spacer that is rotatably mounted about the shaft; and
an outer spacer that is movably mounted on the inner spacer.

46. The implant of claim 45 wherein:

the inner spacer has one of flattened or slightly radiused upper and lower surfaces and rounded ends; and

the outer spacer has one of flattened or slightly radiused upper and lower surfaces and rounded ends.

47. An implant adapted to be placed between spinous processes comprising:

a body includes a shaft; wherein the shaft is radiopaque;

a spacer rotatably mounted on the shaft;

a tissue expander extending from the shaft;

wherein the tissue expander is at least in part radiolucent; and

wherein the tissue expander is at least in part selected from the group consisting of

polyetheretherketone, polyetherketoneketone, polyaryletheretherketone,

polyetherketone, polyetherketoneetherketoneketone, and polyetheretherketoneketone,

wherein the tissue expander distracts the soft tissue and the spinous processes while not impairing the ability to view the spinous processes in an x-ray.

48. The implant of claim 47 wherein the spacer is at least in part selected from the

group consisting of polyetheretherketone, polyetherketoneketone,

polyaryletheretherketone, polyetherketone, polyetherketoneetherketoneketone, and

polyetheretherketoneketone.

49. The implant of claim 37 wherein the body includes a first wing extending from a location on the shaft on an opposite side of the spacer from which the tissue expander extends.

50. The implant of claim 47 wherein the tissue expander has a generally increasing cross-section from a distal end to a location adjacent to the spacer.

51. The implant of claim 49 wherein the body and the first wing are radiopaque such that under imaging the implant resembles a T-shape.

52. The implant of claim 48 further including:

a first wing located at one end of the shaft and a second wing located adjacent to the tissue expander such that the spacer is located between the first and the second wings, wherein the body, the shaft, and the first and second wings are radiopaque such that under imaging the implant resembles an H-shape.

53. The implant of claim 47 wherein the shaft includes an attachment to which the tissue expander is affixed.

54. The implant of claim 47 wherein the spacer has a dimension selected from the group consisting of 6 mm, 8 mm, 10 m, 12 mm, and 14 mm.

55. The implant of claim 47 wherein the spacer has a cross-sectional shape selected from the group consisting of elliptical-shaped, cylindrical-shaped, ovoid-shaped, oval-shaped, track-shaped, and rectangular-shaped with curved ends.

56. The implant of claim 47 wherein the spacer has an off-center bore that receives the shaft so that the spacer can rotate about the shaft.

57. The implant of claim 47 wherein the shaft includes an attachment to which the tissue expander is molded.

58. The implant of claim 57 wherein the attachment includes a device for receiving a wing.

59. The implant or claim 58 wherein the attachment includes a device for receiving a wing.

60. The implant of claim 47 wherein the spacer includes:
an inner spacer that is rotatably mounted about the shaft; and
an outer spacer that is movably mounted on the inner spacer.

61. The implant of claim 60 wherein:
the inner spacer has one of flattened or slightly radiused upper and lower surfaces and rounded ends; and

the outer spacer has one of flattened or slightly radiused upper and lower surfaces and rounded ends.

62. An implant adapted to be placed between spinous processes comprising:

a body having a shaft extending therefrom;

a spacer rotatably mounted on the shaft; and

a tissue expander extending from the shaft,

wherein the body and the shaft are radiopaque, and further wherein the spacer and the

tissue expander are radiolucent, wherein the partially radiolucent tissue expander

distracts the soft tissue and the spinous processes while not impairing the ability to view the spinous processes in an x-ray.

63. The implant of claim 62 wherein the spacer and tissue expander are selected from the group consisting of polyetheretherketone and polyetherketoneketone.

64. The implant of claim 62 wherein the spacer is comprised of: an inner spacer that is rotatably mounted about the shaft; and an outer spacer that is movably mounted relative to the inner spacer.

65. The implant of claim 62 wherein:

the inner spacer has one of a flattened or a slightly radiused upper and lower surfaces and rounded first and second end; and

the outer spacer has one of a flattened or a slightly radiused upper and lower surfaces and rounded first and second ends.

66. The implant of claim 64 wherein the inner spacer and the outer spacer are selected from the group consisting of polyetheretherketone, polyetherketoneketone, and polyaryletheretherketone.

67. The implant of claim 62 further comprising a first and second wing, wherein the wings are located at opposite ends of the spacer and wherein the body, shaft and wings are a radiopaque "H" on imaging film.

(IX). EVIDENCE APPENDIX

None

(X.) RELATED PROCEEDINGS APPENDIX

None.

Respectfully submitted,

COATS & BENNETT, P.L.L.C.

A handwritten signature in dark ink, appearing to read 'D. Kalish', is written over a horizontal line.

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